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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/525,044	08/01/2005	Giorgio Mari	7B901-002US1	5665

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EXAMINER	
BASS, DIRK R	

ART UNIT	PAPER NUMBER
1797	

NOTIFICATION DATE	DELIVERY MODE
07/06/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

INFO@ORTPATENT.COM

Office Action Summary	Application No.	Applicant(s)	
	10/525,044	MARI ET AL.	
	Examiner	Art Unit	
	DIRK BASS	1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 April 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-10,12 and 14-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 3-10, 12, 14-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's response filed April 9, 2010 is acknowledged. Claim 9 is amended. Claims 1, 3-10, 12, and 14-21 are pending and further considered on the merits.

Response to Amendment

In response to the amendment, the examiner withdraws the 35 U.S.C. 102(b) rejections and maintains all other grounds of rejection set forth in the office action dated December 17, 2009.

Claim Rejections - 35 USC § 103

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

2. **Claims 1, 3, 7-10, 12, 16-18, and 20-21** are rejected under 35 U.S.C. 103(a) as obvious over Bormann et al., WO 00/548743 (Bormann) in view of Majurel, EP 0542655 (Majurel). For the purposes of clarity, the examiner is relying on the US publication of Bormann (US 6945411) for the remainder of this office action.

3. Regarding claims 1, 12, 20-21, Bormann discloses a filter device for the depletion of leukocytes (abstract) comprising: a housing having an inlet and an outlet (fig. 2-3), within said housing, more than two porous elements (REF 1, 2), each porous element comprising multiple layers of filtering material (col. 7, l. 42-50) and having different hydrophilicity (col. 8, l. 8-27), said more than two porous elements having a hydrophilicity higher than 63 dyn/cm, and a difference between the inlet porous element and the outlet porous element is at least 20 dyn/cm (col. 8, l. 8-27).

4. Bormann does not appear to explicitly disclose a hydrophilicity 'gradient' between successive filters where more than two filter elements are present. However, it is well known by a person having ordinary skill in the art to increase the hydrophobicity of the membranes from inlet to outlet in a leukocyte depletion filter to increase efficiency, as disclosed by Majurel. Majurel discloses a filtration device with different layers having increasing hydrophobicity from inlet to outlet, the increasing hydrophobicity of the layers improves the separation of blood components (Abstract). Further, it has been generally recognized that to shift location of parts when the operation of the device is not

otherwise changed is within the level of ordinary skill in the art. In re Japikse, 86 USPQ 70; In re Gazda 104 USPQ 400.

5. Further, it would be obvious to one of ordinary skill in the art to use the teachings of these references to arrive at applicant's invention because it produces no more than predictable results. See KSR Int'l. v. Teleflex Inc., 127 S. Ct. 1727, 1732, 82 USPQ2d 1385, 1390 (2007). "it is commonsense that familiar items have obvious uses beyond their primary purposes, and a person of ordinary skill often will be able to fit the teachings of multiple patents together like pieces of a puzzle". "The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results". Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made.

6. Regarding claim 3, Bormann discloses each porous element comprises at least two adjacent layers of filtering material (col. 7, l. 42-50).

7. Regarding claim 7, Bormann discloses said porous elements are made of fibers consisting of polyolefin (col. 7, l. 32-41).

8. Regarding claim 8, Bormann discloses said hydrophilic polymer is acrylic polymers (col. 9, l. 42-50).

9. Regarding claim 9, Bormann is relied upon in the rejection of claim 1 set forth above. Boremann further discloses the porous elements are made of polybutylene terephthalate (col. 7, l. 32-37), where first porous element can be coated with a hydrophilic polymer and the second element can be uncoated (col. 7, l. 51 – col. 8, l. 3).

10. Regarding claim 10, Bormann discloses the porous elements are arranged in the filter device according to a decreasing value of the CWST (col. 8, l. 8-27).

11. Regarding claim 16, Bormann discloses a blood bag device for the separation of blood into leukocyte depleted blood components (fig. 4), comprising a first bag (REF 51) in fluid communication with a second bag (REF 50) through a leukocyte filter device (REF 100) according to claim 1.

12. Regarding claim 17, Bormann discloses a method for leukocyte depletion of blood products comprising feeding said blood product through a filter device according to claim 1 (col. 4, l. 11-21).

13. Regarding claim 18, Bormann discloses said blood product is plasma (col. 4, l. 11-21).

14. **Claims 4-5** are rejected under 35 U.S.C. 103(a) as being unpatentable over Bormann in view of Majurel, and in further view of Pall, US 4925572 (Pall).

15. Regarding claims 4-5, Bormann discloses layers of filtering material in the porous element (Pg. 11, Lines 12-14). Bormann does not appear to explicitly disclose that the layers are made of the same material and subsequently have the same hydrophilicity properties. However, Pall discloses the use of multiple layers in a filter element made of the same material and the material inherently has the same hydrophilicity properties, absent evidence to the contrary (col. 28, l. 7-14); and that the filter elements can have different and varied pore structures (col. 10, l. 45-47).

16. At the time of the invention, it would have been obvious to one of ordinary skill in the art to modify the filter material of the layers of Bormann to include layers of the same material of Pall. The suggestion would have been that Pall discloses layers having a decreasing pore size from inlet to outlet (col. 15, l. 55-59) to efficiently remove microaggregates and leukocytes.

17. **Claim 6** is rejected under 35 U.S.C. 103(a) as being unpatentable over Bormann in view of Majurel, and in further view of Oka et al., US 5298165 (Oka).

18. Regarding claim 6, Bormann discloses that the filter elements can have different and varied pore structures (col. 10, l. 45-47). BORMANN does not appear to explicitly disclose that the filter elements have decreasing pore size from inlet to outlet. However, OKA discloses two layers have a decreasing pore size from inlet to outlet, where the filtering material has a pore size higher than its successive porous element (OKA, Claims 1-2).

19. At the time of the invention, it would have been obvious to one of ordinary skill in the art to modify the different pore structures of the filter elements of BORMANN to include the decreasing pore size from inlet to outlet of the porous elements of OKA.

The motivation would have been to more effectively remove leukocytes from a blood product (Abstract).

20. **Claims 14-15, 19** are rejected under 35 U.S.C. 103(a) as being unpatentable over Bormann in view of Majurel, and in further view of Heagle et al., US 5190657 (Heagle).

21. Regarding claims 14 and 19, Bormann is relied upon in the rejections set forth above. Bormann does not appear to explicitly disclose the use of a filtration element which is not adapted for leukocyte removal. However, HEAGLE discloses a pre-filter (Fig. 6, Ref. 15) which is not adapted for leukocyte removal and instead remove of agglomerates, the pre-filter is made from woven, non-woven textile materials or metal meshes *[microaggregate filtration elements]* (col. 14, l. 9-16).

22. At the time of the invention, it would have been obvious to one of ordinary skill in the art to modify the filtration device for leukocyte depletion of Bormann to include the pre-filter element which is not adapted for leukocyte removal of Heagle. The suggestion would have been to remove large agglomerates prior to contact with the filter element (col. 14, l. 9-16).

23. Regarding claim 15, Heagle further discloses said filter elements not adapted for leukocyte removal are located closer to the inlet than said elements adapted for leukocyte removal (fig. 6).

Response to Arguments

24. Applicant's arguments filed April 9, 2010 have been fully considered but they are not persuasive.

25. In response to applicant's arguments, the examiner provides supporting evidence to obviate the hydrophilicity gradient feature of applicant's claims. Majurel is relied upon to teach a filtration device with different layers having increasing hydrophobicity from inlet to outlet, the increasing hydrophobicity of the layers improves the separation of blood components (Abstract). In light of this teaching, it would have been obvious to one skilled in the art to modify the filter element of Bormann to include the hydrophilicity gradient as recited in claim 1, since it yields no more than predictable results.

26. In response to applicant's argument that Majurel is nonanalogous art, it has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, Majurel is concerned with the particular problem with which the applicant is concerned, namely a hydrophilicity gradient within a filter element. Therefore, the examiner maintains that Majurel is relevant and applicable to the above stated rejections.

27. In response to applicant's arguments regarding the use of Pall for the rejection of claims 4 and 5, the examiner reminds applicant that Pall is cited to teach filter elements which are composed of the same material. Arguments with respect to the functionality of the secondary reference are not considered since Bormann clearly teaches leukocyte removal filters and Pall is relied upon to teach porous elements having the same material construction.

Conclusion

28. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DIRK BASS whose telephone number is (571) 270-7370. The examiner can normally be reached on Mon - Fri (9am-4pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Vickie Kim can be reached on (571) 272-0579. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Krishnan S Menon/
Primary Examiner, Art Unit 1797

/DRB/
Dirk R. Bass